



SRITONG GROUP

HEALTHY GLOVE CO., LTD

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169 หมู่ที่ 4 ตำบลลำทับ อำเภอลำทับ จังหวัดกระบี่ 81120 โทร. 081-9597933 โทรสาร 074-245061

EC DECLARATION OF CONFORMITY

Plant of Manufacture : 119 Kanchanavanich Road, Tambol Patong, Hatyai,
Songkhla 90230, Thailand

Product : Power Free Nitrile Rubber Examination Gloves.

Intended Use : For the covering of hands of medical staff during
examination procedures involving patient body surfaces
and patient body orifices.

The undersigned hereby declares, on behalf of **Healthy Glove Co., Ltd**, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of Medical devices directive 93/42/EEC.

Healthy Glove Co., Ltd's quality management system has been certified by TÜV Süd for the manufacture of natural and synthetic latex examination gloves, and in compliance with the requirements of ISO 9001:2008 and ISO 13485:2003.

All supporting documentation is retained under the premises of the manufacturers.

Reference Standards :

En 455-1 : Medical gloves for single use - part 1
Requirements and testing for freedom from holes.

EN 455-2 : Medical gloves for single use - part 2
Requirements and testing for physical properties.

EN 455-3 : Medical gloves for single use - part 3
Requirements and testing for Biological Evaluation

EN455-4 : Medical gloves for single use - part 4
Requirements and testing for shelf life determination.

Signed / Stamped by

Name : Teoh Choh Shee

Position : Managing Director

Date : 6/5/15